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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/115,589	07/15/1998	JENNIFER E. VAN EYK	12917	1553

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EXAMINER
GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/115,589	Van Eyk et al.
Examiner	**Group Art Unit**
Stephen Rucker	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 10/23/02.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-28 + 53-55 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☑ Claim(s) 5 is/are allowed.

☑ Claim(s) 1-4, 6-28 + 53-55 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Stat ment(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Pat nt Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Response to Amendment

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

2. Claims 1-4, 6-24, 28, and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (WO 94/27156, "Wicks"). Wicks discloses the use of antibodies and detectable labels and markers (enzymes, alkaline phosphatase, page 12) to detect troponin I (and specific fragments claimed, page 5 and claims 12-13, 18, 26-27, 32-34, and 36) and troponin C in a

complex in sandwich assays having immobilized solid phases for the purpose of assaying irreversible cardiac damage from biological samples such as blood (pages 2-5).

*Applicant's arguments filed 4/19/01 have been fully considered but they are not persuasive because Applicant argues that a method for assessing muscle damage in a subject by evaluating for the presence or absence of a "**myofilament protein modification product**" as defined by the instant specification is absent from Wicks. The specification defines the phrase "myofilament protein modification product" very broadly, such that it encompasses multiple proteins (troponin I, troponin T, troponin C, myosin light chain 1, α-actin, etc.) and all fragments of these proteins, in addition to covalent or non-covalent complexes of two or more intact proteins or any fragments of these proteins. Furthermore, the phrase also encompasses covalent or non-covalent complexes of any myofilament protein or any fragment thereof with any other non-myofilament protein or any fragment thereof (see page 10, line 21 to page 11, line 15). The Examiner maintains that Wicks meets all the limitations of the claims when he teaches methods to detect troponin I and troponin C in a complex because any complex formation, covalent or non-covalent, is encompassed by the instant claims as defined by the phrase "myofilament protein modification product" as defined by the instant specification. Contrary to Applicant's assertion, Wicks is drawn to methods of detecting muscle (cardiac) damage, see pages 1-2 of Wicks, especially page 2, lines 11-16. Wicks teaches detecting troponin I and his methods can detect different fragments of troponin I, meeting the claim limitations of two different myofilament protein modification products because the broad phrase encompasses two*

different fragments as defined by the instant specification. The methods of Wicks using antibodies raised against troponin I fragments would inherently detect the fragments themselves, again meeting the broad limitations of the claims. The use of the antibodies and processes of Wicks inherently meets all claim limitations, even if the intent is not to detect cardiac troponin I fragments per se (Ex parte Novitski, 26 USPQ 1391).

3. Claims 1-2, 8-21, 25-28, 53, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (WO 96/10078, "Takahashi"). Takahashi discloses the use of antibodies and detectable labels and markers (enzymes, peroxidase and alkaline phosphatase, pages 6-7 and 9) to detect myosin light chain 1 (MLC-1) in a complex in sandwich assays having immobilized solid phases (pages 10 and 12) for the purpose of assaying irreversible cardiac damage from biological samples such as blood (pages 2-5).

*Applicant's arguments filed 4/19/01 have been fully considered but they are not persuasive because Applicant argues that a method for assessing muscle damage in a subject by evaluating for the presence or absence of a "**myofilament protein modification product**" as defined by the instant specification is absent from Wicks. The specification defines the phrase "myofilament protein modification product" very broadly, such that it encompasses multiple proteins (troponin I, troponin T, troponin C, myosin light chain 1, α-actin, etc.) and all fragments of these proteins, in addition to covalent or non-covalent complexes of two or more intact proteins or any fragments of these proteins. Furthermore, the phrase also encompasses covalent or non-covalent complexes of any myofilament protein or any fragment thereof with any*

other non-myofilament protein or any fragment thereof (see page 10, line 21 to page 11, line 15). Like Wicks, the use of the antibodies and processes of Takahashi would detect not only MLC-1, but fragments of MLC-1 from the amino terminal of MLC-1 because that is what the antibodies of Takahashi were raised against (see abstract). Takahashi inherently meets all claim limitations, even if the intent is not to detect cardiac MLC-1 fragments per se (Ex parte Novitski, 26 USPQ 1391).

4. Claim 5 is in condition for allowance.

5. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

6. Applicant must comply with the sequence rules and the remainder of the enitre Office action simultaneously. Otherwise, the applicant will receive a Notice of Non-Responsive Reply.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

May 28, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600